MEDICAL DEVICE FOR ANALYTE MONITORING AND DRUG DELIVERY

This application is a divisional of U.S. Ser. No. 10/937,872 filed on Sep. 10, 2004 now U.S. Pat. No. 7,291,497, which claims priority to U.S. Ser. No. 60/501,847 filed Sep. 11, 2003.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to the fields of diagnosis and drug delivery. More particularly it relates to medical devices and methods capable of monitoring levels of a bodily fluid analyte and optionally releasing of appropriate therapeutic agents.

2. Background

"Point of care" devices that are capable of detecting biological macromolecular activity or drug concentration levels are in high demand because they eliminate the need for patient lab visits, thus providing savings in both time and expense. One of the most valuable aspects of modern microarray technology is the ability to detect biological macromolecular dysfunction, malformation or mutation resulting in disease. However, this capability has not been fully exploited because such arrays have not been incorporated into ingestible, implantable or wearable point of care devices. Modern microarray technology is limited to characterization of biological macromolecules and their metabolites by analysis of immobilized analytes stabilized on slides to be inserted into a machine or analyzed manually outside of living organisms.

Because whole blood contains cells, platelets, a myriad of proteins and other macromolecules, assays involving blood typically require pre-processing of the sample to remove these components. Integrating pre-processing steps into a point of care device drives up the cost of the device itself, thus making use of the device financially unviable. For example, some devices currently on the market using whole blood in their assays; among them are Boehringer Mannheim's Reflotron™ system for measuring blood borne analytes (most notably cholesterol) and the iStat™ (iStat Inc.), which performs a number of critical care assays, including electrolytes, general chemistries, blood gases and hematology. The Reflotron™ relies on dry chemistry technology in which enzymes or other reactive elements are immobilized on the surface of a test strip. The assay is a calorimetric activity assay in which the reaction produces a color change and is thus indicative of the amount of analyte present. The iStat™ relies on electrochemical detection to produce a signal. In either case, a blood sample is taken separately (typically by a finger prick) and then placed on the chip (or cartridge in the case of the istat), where the reaction occurs and is analyzed by an external detection unit These existing monitoring systems are insufficient and inconvenient as they usually require the user to prick themselves and multiple steps to obtain a result. As such, there is a need for a wearable device that can repeatedly, automatically and accurately monitor bodily fluids such as blood.

Point of care devices are also useful in certain situations where systemic biological samples such as blood, urine or stool, cannot provide adequate information as to subtle molecular changes at the situs of disease. In such a case, even if the clinician could pinpoint the exact situs of an ailment, obtaining a biological sample for analysis comes only at great risk, pain and expense for the patient. Additionally, a point of care device would be desirable where the systemic administration of drug agents, such as by transdermal or intravenous

means, treats the body as a whole even though the disease to be treated may be localized. Here, systemic administration may not be desirable because the drug agents often have unwanted effects on parts of the body that are not intended to be treated, or because treatment of the diseased part of the body requires a high concentration of drug agent that may not be achievable by systemic administration. For example, when administered to a patient systemically, some drugs (e.g., chemotherapeutic drugs such as those used to treat cancer and other proliferative disorders) may cause undesirable side effects. It is therefore often desirable to detect disease and administer drug agents at a localized site within the body.

As such there is a demand for point of care devices capable of detecting biological macromolecular activity or drug concentration levels that may also administer a specific therapeutic agent at a localized site within the body in response to changes in biological macromolecular activity or drug concentration levels. All articles, publications and patents cited herein are incorporated by reference in their entirety for all purposes. Additionally, provisional patent application Ser. No. 60/501,847 filed Sep. 11, 2003, is hereby incorporated by reference.

SUMMARY OF THE INVENTION

One aspect of the invention relates to a medical device comprising a microarray which comprises a bioactive agent capable of interacting with a disease marker biological analyte; a reservoir which comprises at least one therapeutic agent and is capable of releasing the therapeutic agent(s) from the medical device; and a plurality of microchips comprising a microarray scanning device capable of obtaining physical parameter data of an interaction between the disease marker biological analyte with the bioactive agent; a biometric recognition device capable of comparing the physical parameter data with an analyte interaction profile; a therapeutic agent releasing device capable of controlling release of the therapeutic agent from the reservoirs; an interface device capable of facilitating communications between the microarray scanning device, biometric recognition device and the therapeutic agent releasing device; and an energy source to power the medical device.

In one embodiment of this aspect of the invention the device is coated and the coating is a biostable polymer which may have channels. In another embodiment of this aspect of the invention, the polymer is porous.

In a different embodiment, bodily fluids are transported through microfluidic lanes which move molecules by means of pressure differences over the microarray. In one embodiment, an osmotic pump is used to propel the fluids through the top portion of the device. In another embodiment fluid transport is powered by natural electric currents in the body conducted through Personal Area Network technology.

In yet another embodiment of this aspect of the invention, the microarray comprises microbeads. In another embodiment, the bioactive agent is a nucleic acid. In yet another embodiment, the bioactive agent is a polypeptide. In yet another embodiment, the bioactive agent is an immunoglobulin.

In an additional embodiment of the medical devices of the invention, the bioactive agent is fluorescently labeled. In another embodiment, the bioactive agent is fluorescently labeled with a nanocrystal.

In yet another embodiment, the disease marker biological analyte is a nucleic acid. In a further embodiment, the disease